REMARKS

Claims 30-49 are pending in the application. Favorable reconsideration in light of the enclosed Rule 132 Declaration and the remarks which follow is respectfully requested. Since the Rule 132 Declaration places the application in condition for allowance, removes issues in the event of an appeal, and does not require further searching, entry is respectfully requested.

The Art Rejection

Claims 30-49 have been rejected under 35 U.S.C. § 102(e) over Reich et al (U.S. Patent 6,090,995). Reich et al relates to synthetic surfaces having a surface modifier composition attached thereto, and an epithelial cell supporting coating on the surface modifier composition. The surface modifier composition is a polymer with a plurality of pendant groups, and the pendant groups are functionalized so that they covalently bond to the synthetic surface. The epithelial cell supporting coating may contain collagen, fibronectin, laminin, heparin, heparin sulfate proteoglycan, and chondroitin sulfate, among others. The functionalized pendant groups of the surface modifier composition also serve to bind the epithelial cell supporting coating.

The Examiner contends that Reich et al uses the same materials (such as collagen and heparin sulfate) and that the materials are hemocompatible.

To establish anticipation, each and every claim feature must be disclosed in a single cited art document. Claims 30, 39, and 47 require a hemocompatible surface containing a constituent of an outer layer of a blood cell or a mesothelial cell or a combination thereof. Reich et al fails to disclose a hemocompatible surface containing a constituent of an outer layer of a blood cell or a mesothelial cell or a combination thereof. While Reich et al discloses certain materials, none of the materials listed by Reich et al are obtained from an outer layer of a blood cell or a mesothelial cell. Since Reich et al does not disclose all of the claimed features, and especially any material from an outer layer of a blood cell or a mesothelial cell Reich et al cannot anticipate claims 30-49.

Further in support of the fact that the constituent of a blood cell or a mesothelial cell required by claims 30, 39, and 47 is different from the materials of Reich et al, a Rule 132 Declaration is enclosed. Specifically, experiments were performed to demonstrate the differences of constituents obtained from an outer layer of a blood cell or a mesothelial cell versus like named compounds that are not obtained from a blood cell or a mesothelial cell. The experiments show the hemocompatible potential of substances isolated from erythrocytes and mesothelial cell glycocalices in relation to materials not obtained from blood cells or mesothelial cells.

The constituent of blood cells or mesothelial cells as well as the materials of Reich et al were covalently immobilized on cellulose membranes and then subjected to *in vitro* blood tests in order to determine blood platelet adhesion on the membrane surface. Measuring platelet adhesion is a well-established method to determine the thrombogenicity of foreign surfaces. A high number of deposited thrombocytes means low hemocompatibility while low or no deposition of thrombocytes means high hemocompatibility.

The test results clearly show that constituents of blood cells or mesothelial cells are different from the materials of Reich et al. Both groups of materials are subjected to the same preparation and experimental conditions. The high hemocompatibility of the claimed materials (~0% coverage) is superior to that of materials that are NOT constituents of blood cells or mesothelial cells. See the Figure on page 6 in Rule 132 Declaration. For example, the most hemocompatible commercially available material was heparin sulfate from swine intestinal mucosa (HS), which exhibited moderate thrombocyte adhesion (10% coverage). This moderate thrombocyte adhesion is insufficient to establish hemocompatibility, and thus the claimed materials are not only different from, but also superior to materials mentioned by Reich et al that are not constituents of blood cells or mesothelial cells.

Furthermore, Reich et al fails to teach or suggest the hemocompatibility (neither activating nor suppressing a blood coagulation system) required in claims 30, 39, and 47 that results from the use of materials obtained from outer layers of blood cells, outer

layers of mesothelial cells. The Examiner states that according to Reich et al, the use of heparin sulfate (a polysaccharide constituent of an outer layer of a blood cell) to achieve hemocompatibility would be obvious to one skilled in the art, and that how or where the heparin sulfate is obtained is not given patentable weight. Applicants respectfully disagree for at least the following two additional reasons.

First, Reich et al is primarily concerned with incorporating into the surface modifier compositions biological materials which are known to support growth, migration and attachment of epithelial cells (see Column 4, lines 52-55; claims 4 and 11). One skilled in the art would therefore interpret Reich et al to describe a general method for fixation of a device relative to other tissues and/or for cosmetic purposes, and a specific method for subepithelial implantation and epikeratophakia lenses. Claims 30, 39, and 47 describe the required hemocompatibility, which does not involve fixation of a device relative to other tissues and/or cosmetic purposes. Additionally, to achieve the desired hemocompatibility, one must avoid incorporating materials that support growth, migration, and attachment of epithelial cells. Hemocompatibility requires that few if any cells in the blood coagulation system interact with a given device such that the blood coagulation system is not activated nor suppressed. It is noted that hemocompatibility is neither explicitly mentioned nor suggested by Reich et al.

Second, Reich et al envisions a device being coupled with biological materials selected from the group consisting of antibiotics, antimicrobial agents, antiviral agents, anti-inflammatory agents, anti-protease agents, hormones, vitamins, analgesics, chelating agents, and mitogenic agents (see claims 5 and 12). Each of these biological materials is commercially available and has a pharmaceutical effect. The claimed materials are neither commercially available nor intended to have any pharmaceutical effect. For example, coupling the device with material derived from the glycocalix has the effect of making the device behave more like the surrounding tissue, rather than having any pharmaceutical effect, such as anti-microbial activity. Claims 30,39, and 47 recite that the hemocompatible surface does neither activate nor actively suppress a blood coagulation system. Thus, hemocompatibility is not a pharmaceutical effect and

consequently hemocompatibility is not obvious from Reich et al.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-1063.

Respectfully submitted,

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